K093221

DENTSPLY

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872
(800) 877-0020
Fax (717) 849-4343
www.dentsply.com

510(k) SUMMARY
for
Pre-Cemented Orthodontic Bracket system Extension II

06. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

OCT 3 0 2009

Date Prepared: 7 October 2009

2. Device Name:
   - Proprietary Name: Pre-Cemented Orthodontic Bracket System Extension II
   - Classification Name: Adhesive, bracket and tooth conditioner, resin
   - CFR Number: 872.3750
   - Device Class: II
   - Product Code: DYH

3. Sponsor's Predicate Device:

Company	Device	510(k) Number	Date Cleared
DENTSPLY International, Inc.	Pre-Cemented Orthodontic Bracket System	K061252	02/12/2007
DENTSPLY International, Inc.	Pre-Cemented Orthodontic Bracket System Extension	K081291	05/22/2008

4. Description of Device:
The Pre-Cemented Orthodontic Bracket System Extension II is comprised of pre-cemented ceramic and metal orthodontic brackets, transfer tray and adhesives.

5. Indications for Use:
Pre-Cemented Orthodontic Bracket System Extension II is indicated for use in bonding orthodontic appliances for orthodontic treatment.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.
The Pre-Cemented Orthodontic Bracket System Extension II represents an addition of K081291.

All of the components found in the Pre-Cemented Orthodontic Bracket System Extension II have been used in legally marketed devices and/or were found safe for dental use. Since there is no change in the super mesh base for both the metal and ceramic brackets, shear bond strength testing, Failure Mode Effect Analysis (FMEA) and biocompatibility testing was not necessary.

We believe that the prior use of the component of the Pre-Cemented Orthodontic Bracket System Extension II in legally marketed devices, the performance data provided, and the previous biocompatibility data provided support the safety and effectiveness of Pre-Cemented Orthodontic Bracket System Extension II for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 3 0 2009

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K093221
Trade/Device Name: Pre-Cemented Orthodontic Bracket System Extension II
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Codes: DYH, NJM, and EJF
Dated: October 7, 2009
Received: October 13, 2009

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093221

Device Name: Pre-Cemented Orthodontic Bracket System Extension II

Indications for Use:

Pre-Cemented Orthodontic Bracket System Extension II is indicated for use in bonding orthodontic appliances for orthodontic treatment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Melby for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093221